K080862

KLS martin L.P.

JUL 21 2008

510(K) SUMMARY

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Tom Faucett RA/QA Supervisor
Date of Summary:	18 March 2008
Device Name:	SonicWeld RX (Resorb-X)
Trade Name:	SonicWeld RX (Resorb-X)
Common Name:	Bone Plate
Classification Name and Number:	Bone Plate (872.4760)
Regulatory Class:	II
Predicate Devices:	Resorb-X Resorbable Plating System (K011590) Resorb-X SF (K051236) Synthes (USA) Rapid Resorbable Fixation System (K062789)
Intended Use:	The KLS Martin SonicWeld RX (Resorb-X) is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, plates, screws and pins may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation. The KLS Martin SonicWeld RX (Resorb-X) is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

The SonicWeld Rx pins are designed only to be inserted with the SonicWeld Rx Sonotrode device.

Device Description:

The SonicWeld RX (Resorb-X) is identical to RESORB-X® SF (K051236) which consists of RESORB-X® Pins made of Poly (D, L) - Lactide-Acid (PDLLA) of various diameters and lengths that are implanted utilizing ultrasonic force generated by an ultrasonic unit that causes a phase transition in the pin, allowing the pin to adapt to the previously drilled pilot hole in the surgical site and utilize the micro undercuts of the bone for retention. The RESORB-X® SF pins are designed to be used in conjunction with RESORB-X® Resorbable Plating System plates (K011590).

Technological Characteristics:

Similarities to Predicate

The SonicWeld RX (Resorb-X) is identical to RESORB-X Resorbable Plating System (K011590) Resorb-X SF (K051236) in chemical composition.

The SonicWeld RX (Resorb-X) are the identical pins, screws and plates as the RESORB-X Resorbable Plating System (K011590) and Resorb-X SF (K051236) and are implanted in the identical manner.

Differences to Predicate

This submission expands the indications for use to include use in non-load bearing applications in the mandible.

Substantial Equivalence:

The SonicWeld RX (Resorb-X)is substantially equivalent in intended use to the RESORB-X Resorbable Plating System (K011590), Resorb-X SF (K051236) and the Synthes (USA) Rapid Resorbable Fixation System (K062789)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom Faucett
Senior Regulatory Affairs/ Quality Assurance Specialist
KLS Martin L.P.
11239 St. Johns Industrial Parkway South
Jacksonville Florida 32246

JUL 21 2008

Re: K080862
Trade/Device Name: SonicWeld RX (Resorb-X)
~~Regulation Number~~: ~~872.4760~~
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: June 17, 2008
Received: June 18, 2008

Dear Mr. Faucett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080862

Device Name: SonicWeld RX (Resorb-X)

Indications For Use: The KLS Martin SonicWeld RX (Resorb-X) is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, plates, ~~screws and pins~~ may be ~~used in non-load bearing applications for~~ maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.
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Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

~~(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF~~ NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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